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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/778,154	02/05/2001	Seo Hong Yoo	APAP31191-A 072852.0117	5489
31625 7590 01/25/2007 BAKER BOTTS L.L.P. PATENT DEPARTMENT 98 SAN JACINTO BLVD., SUITE 1500 AUSTIN, TX 78701-4039			EXAMINER SHIBUYA, MARK LANCE	
			ART UNIT 1639	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE			MAIL DATE	DELIVERY MODE
3 MONTHS			01/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/778,154

Applicant(s)

YOO, SEO HONG

Examiner

Mark L. Shibuya, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 138-140, 142-148 and 152-155 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 138-140, 142-148 and 152-155 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>6/7/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 138-140, 142-148, 152-155 are pending and examined.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/18/2006 has been entered.

Election/Restrictions

3. The requirement for election of species, as set forth in the Requirement for Restriction/Election, mailed 3/27/2002, is withdrawn hereby.

Priority

4. The instant application states that it is a continuation-in-part of Serial No. 09/357,549, filed 7/20/1999, now US Patent 6,251,428, which claims benefit of 60/094,069, filed 7/24/1998; and claims benefit of US Provisional Application No. 60/180,268, filed 2/4/2000.

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5. Applicant is requested to update the status of priority application 09/357,549, in the first line of the specification.

Information Disclosure Statement

6. The information disclosure statements (IDS) submitted on 6/07/2006 was filed after the mailing date of the Final Rejection on 5/17/2006. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered by the examiner.

Withdrawn Rejections and Objections

7. The following rejections are withdrawn in view of applicant's arguments and amendments to the claims.
8. Claims 138-141 are rejected under 35 U.S.C. 102(b) as being anticipated by Japan Publication No. 62153220, Formal Translation, (IDS filed 5/17/2004) to Shinzo Nakazawa and Satoshi Hisano (English translation of "Nakazawa et al."; also called "Satoshi" by the applicant and in the Yoo Declaration I).
9. Claims 138-141 are rejected under 35 U.S.C. 102(b) as being anticipated by Panini et al., Pharmacological Research, Vol. 31, No. 3/4, 1995.

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10. Claims 138-141 are rejected under 35 U.S.C. 102(b) as being anticipated by Widauer, U.S. Patent No. 5,534,505.

11. Claims 138-141 are rejected under 35 U.S.C. 102(b) as being anticipated by anticipated by Ventura et al., International Journal of Pharmaceutics, vol. 149, (1997), pp. 1-13.

12. Claims 138-147 are rejected under 35 U.S.C. 103(a) as being unpatentable over Japan Publication No. 62153220 to Nakazawa et al., Formal Translation, (IDS filed 5/17/2004) and Acharya et al., US 6,210,699.

13. Independent claim 148 is rejected under 35 U.S.C. 103(a) as being unpatentable over Japan Publication No. 62153220 to Nakazawa et al., Formal Translation, (IDS filed 5/17/2004) and Vandelli et al., International Journal of Pharmaceutics, vol. 118, (1995), pp. 77-83.

Specification

14. The specification is objected to because it is unclear as to which of the numerous amendments to the specification find support in specification as filed. If applicant is unable to provide such a clarification, a substitute specification will be required.

Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 138-140, 142-148, 152-155 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-35 of U.S.

Patent No. 6,251,428 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other.

The claims are drawn to an aqueous solution free of precipitates or particles comprising: (i) a first material selected from the group consisting of an aqueous soluble bile acid salt, a bile acid conjugated with an amine by an amide linkage, and combinations thereof; (ii) a second material selected from the group consisting of maltodextrin, dextrin, corn syrup, corn syrup solid, soluble starch, and dextrans, and combinations thereof; and (iii) water, at least one alkali, and (iv) water, wherein the first

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and second materials both remain in solution for all pH values obtainable in an aqueous system; and variations thereof.

Claims 1-35 of U.S. Patent No. 6,251,428 B1, formerly U.S. Application No. 09/357549, (of which the instant application states that it is a continuation-in-part), are drawn to a clear aqueous solution comprising: (a) a first material selected from the group consisting of a bile acid, an aqueous soluble derivative of a bile acid, a bile acid salt, and a bile acid conjugated with an amine by an amide linkage; (b) a second material selected from the group consisting of dextran and liquid glucose; and (c) water, wherein the first and second materials both remain in solution for all pH values of the solution within a selected range of pH values and wherein the weight ratio of the second material to the first material is less than about 30:1.

Thus the instant claims encompass, and so are obvious over the claimed invention of the U.S. Patent No. 6,251,428 B1.

Conclusion

17. Claims 138-140, 142-148, 152-155 are rejected.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Shibuya whose telephone number is (571) 272-0806. The examiner can normally be reached on M-F, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. James Schultz can be reached on (571) 272-0763. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Mark L. Shibuya, Ph.D.
Primary Examiner
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